

PREMIER DIRECT_{INC.}

245 N.E. 4th Avenue, Suite 201, Delray Beach, Florida 33483
(561) 278-6080 TEL • (561) 278-1139 FAX

July 27, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204



RE: 21 U.S.C. Section 343(r)(6) Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Mid-Life Change, a dietary supplement. Premier Direct, Inc. is a manufacturer of Mid-Life Change.

Statements Being Made in the Labeling of Mid-Life Change

- (1) Support Healthy Hormone Levels and Feel Good Naturally
- (2) support their healthy estrogen and progesterone balance
- (3) fortified with Calcium and Magnesium to help maintain bone strength and density ... vitamins B and E for cardiovascular support.

To the best of my knowledge, and based upon information and belief present at the time of executing this notice, I certify that this information is accurate and complete and Premier Direct, Inc. possesses substantiation that the statements are truthful and not misleading.

A handwritten signature in cursive script, followed by "VP" and a horizontal line.

• 97S - 0162

66458
LET 4014